



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JAN 14 2005

President  
Trader Joe's Company  
Corporate Office  
P.O. Box 5049  
Monrovia, California 91017-7149

Dear Sir:

This is in response to your submission to the Food and Drug Administration (FDA), dated December 27, 2004. Your submission appears to be intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a) for products marketed by Trader Joe's Company as dietary supplements.

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the products that are the subject of the notification to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety,  
and Applied Nutrition

975-0163

LET 804

Page 2 - President, Trader Joe's Company

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

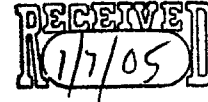
# TRADER JOE'S COMPANY

*Unique foods and beverages at prices everyone can afford*

CORPORATE OFFICE  
P.O. BOX 5049  
MONROVIA, CA 91017-7149  
(626) 599-3700

December 27, 2004

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204



Dear Sirs:

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Distributor's name and address: Trader Joe's Company, P.O. Box 5049, Monrovia, CA 91017

1. Statement: A natural support for restful sleep\*

Dietary ingredient: Melatonin

Name of the supplement: (Trader Darwin's Chewable Peppermint Flavored Melatonin

Dietary Supplement sku # 00481403)

2. Statement: Olive & Oregano Oil Antioxidant Formula\*

Dietary Ingredients: Virgin Olive Oil (Olea Europa), Polyphenols from Grape Leaf powdered Extract (Vitis vinifera), Oregano Oil (Thymus capitatus) (leaf), Lycopene (Lycomatic).

Name of the supplement: (Trader Darwin's Olive & Oregano Oil Antioxidant Formula\*

Dietary Supplement sku # 00751940)

Respectfully submitted,

Trader Joe's Company



**Supplement Facts**  
Serving Size 1 Tablet  
Servings Per Container 100

Amount Per Tablet	% Daily Value
Total Carbohydrate	<1 g <1%*
Sugars	<1 g †
Melatonin	500 mcg †

\* Percent Daily Values are based on a 2000 calorie diet  
† Daily Value not established.

**CHEWABLE**  
PEPPERMINT FLAVORED  
**MELATONIN**  
DIETARY SUPPLEMENT

Exp. Date/Lot

00481403

Composite

**TRADE MARK**  
FOR THE SURVIVAL OF THE Fittest

**OLIVE & OREGANO OIL**  
**ANTIOXIDANT FORMULA\***  
**DIETARY SUPPLEMENT**

**60 SOFTGELS**

**Supplement Facts**

Serving Size 1 Softgel  
Servings Per Container 60

Amount Per Serving	% Daily Value
Calories	6
Calories from Fat	5
Total Fat	0.6 g 1%
Virgin Olive Oil (Olea europaea) (cold pressed) 500 mg	1
Polyphenols From Grape Leaf Powdered Extract (Vitis vinifera)	50 mg 1
Oregano Oil (Origanum capitatum) (leaf)	25 mg 1
Lycopodium (LYC-O-MAT®)	1 mg 1

\* Percent Daily Values are based on a diet of 2000 calories a day.  
† Daily Value not established.

**OTHER INGREDIENTS:** Softgel Capsule (Gelatin, Glycerin, Water), Yellow Oxide Wax, Unbleached Food-Grade Gelatin.

**Dist. & Sold Exclusively By:**  
**Trader Joe's, Menloville, CA 94516**

**PRODUCT OF SPAIN**

Exp. Date/Lot #:

Composite